Tiered Risk Assessment for NTO

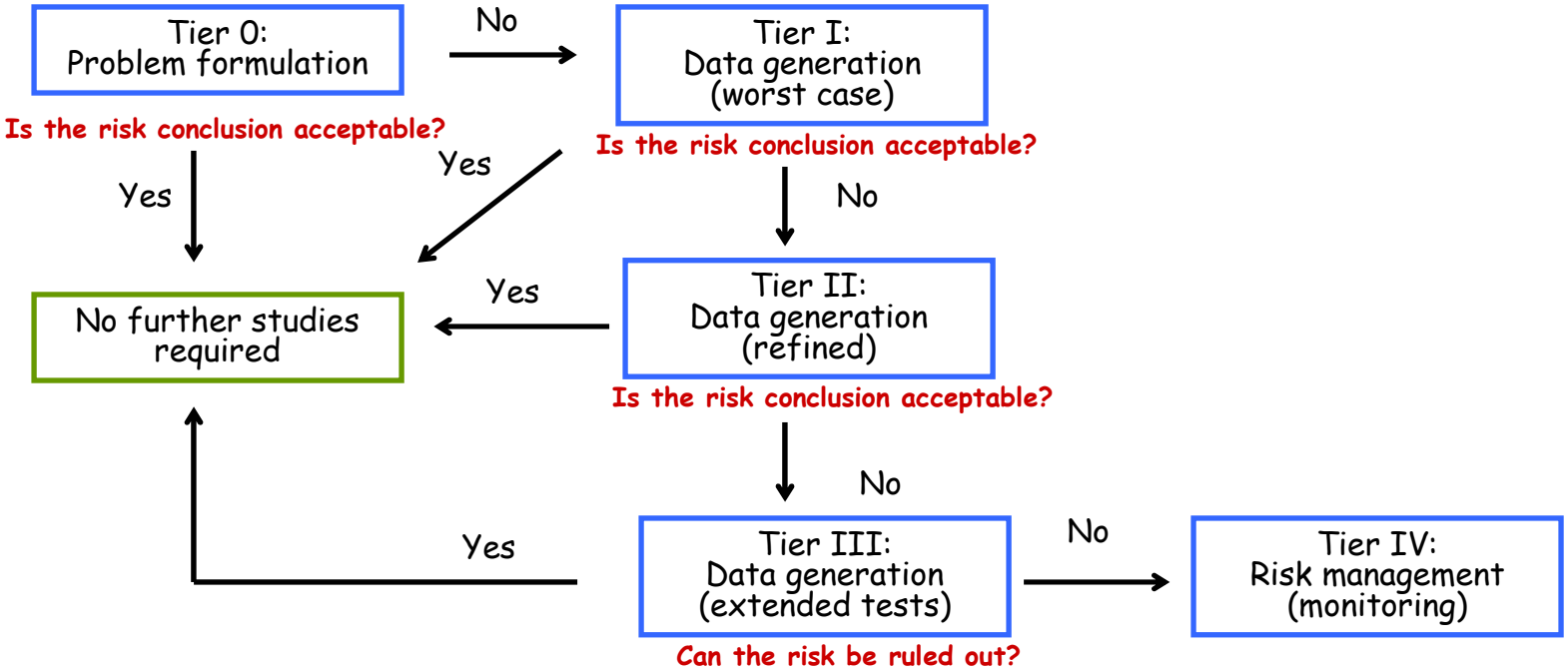
Silvia Fernandez

Workshop " Environmental Risk Assessment for cultivation of GM crops"
15-16 October 2009, Brussels

The tiered approach

A tiered risk assessment is a logical progression of tests to evaluate potential risks

- **Provides practical organization of data generation**
- **Allows rational, science-based decision-making by both registrants and regulators.**

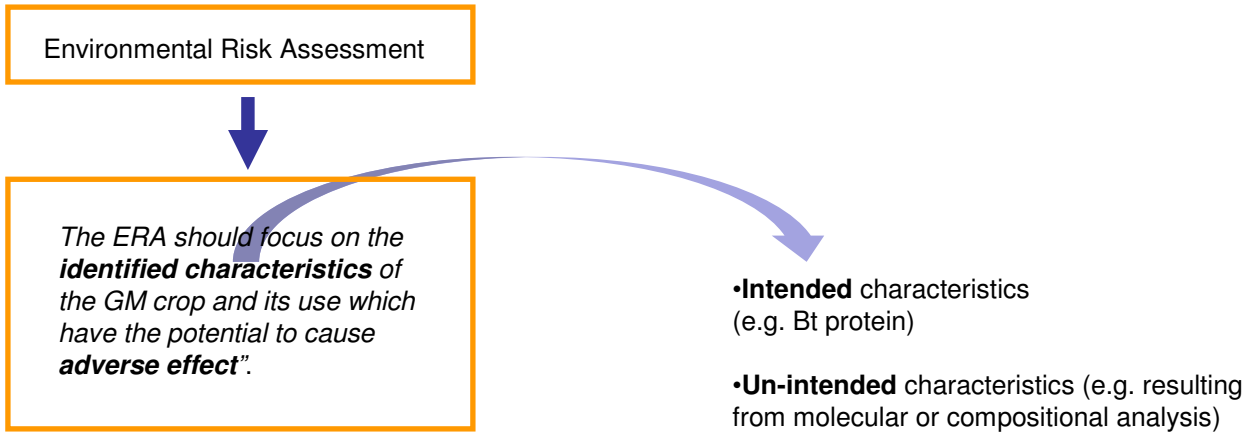


Tiered Risk Assessment for NTO
Tier 0: Problem formulation

Formulation of testable hypothesis:

- Identification of potential risk

  According Directive 2001/18/EC all applications for cultivation of GM crops in the EU have to include:



- Formulation of hypothesis
- Design of studies to test the hypothesis

Data generation for the ERA

- Once potential risks are identified risk assessors formulate testable hypothesis and design appropriate studies that allow to test these hypotheses

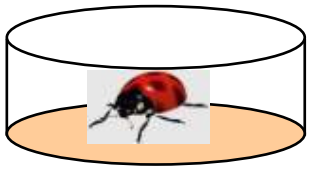
- Study design:

  - What are the study endpoints?
  - Which species can be used to conduct the study?
  - What is the most appropriate test substance?....

Example of studies at different tiers:

Tier I

Worst case:
high concentration (e.g. 10x) in artificial diet



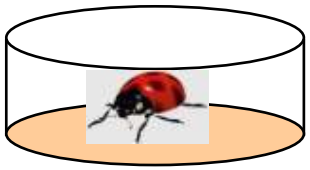
X = Measured concentration in the plant

Adverse effects? — No → No more testing required

Yes ↓

Tier II

Refined:
• more realistic concentration (e.g. 1x)



or

x

• more realistic exposure

Adverse effects? — No ↑

Yes ↓

Tier III

Tier III

Extended tests

Semi-field

And/or

Field

Adverse effects?

No

No more testing required

Yes

Tier IV

Case specific monitoring for the NTO (s) suspected to be at risk

Laboratory versus field studies

	Lab	Field
Pros	•Standardized testing systems •Reproducibility •Focus on specific and clear endpoints •Controlled conditions •Surrogate species •Worst case environmental exposure scenario	•Represent realistic exposure •Many species tested at the same time
Cons	•Focus on one species at a time •Limited availability of validated tests •Representativeness (e.g. species and test substances) •Not necessarily *in-planta*	•No standardized methodology (e.g. trial design) •Variability (e.g. year to year) •Hazard evaluation limited to the level of expression in the crop •Less likely to reveal differences due to multitude of interacting parameters

Summary

- ERA follows a logical / scientific tiered approach
- Focuses on intended and un-intended characteristics of the GM that may cause harm
  - Hypothesis originate in the Problem Formulation tier
- Data in all tiers not necessarily being generated => each tier is a discrete risk assessment
- Ultimate goal of ERA: Decision Making

Thank you!

For more information visit:
Green Biotechnology Europe on the EuropaBio website:
www.europabio.org